IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE LLC, Defendants.	C.A. No. 08-91 (GMS) REDACTED - PUBLIC VERSION

EDWARDS' REPLY BRIEF IN SUPPORT OF MOTION FOR PERMANENT INJUNCTION, ACCOUNTING AND RELATED RELIEF

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I. INTRODUCTION

CoreValve states "many who will bear the burden of this injunction may pay with their lives." (CoreValve Brief ("CV Br.") [D.I. 392] at 20). But an injunction will not remove CoreValve's product from the market. In truth, CoreValve opposes an injunction because it claims it may lose "goodwill among the medical community," and [redacted] (CV Br. at 6, 11; [redacted]

In the days following the April 2010 willful infringement verdict in this case, Medtronic repeatedly and publicly announced that the issuance of an injunction would not compromise the continued treatment of CoreValve's patients. (Edwards Brief ("EW Br.") [D.I. 357] at 12-13). [redacted]

CoreValve's continued infringement should be stopped, not rewarded. By willfully infringing, CoreValve surrendered its right to goodwill in the medical community, [redacted]

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1 [redacted] The February 2008 complaint put CoreValve on notice that Edwards sought an injunction in this case. Medtronic purchased CoreValve in April 2009 with its eyes wide open. Medtronic knew about the Edwards lawsuit and the risk of an injunction. In fact, Medtronic's involvement with CoreValve dates back to 2003, long before the 2009 acquisition. (*See* Edwards Reply in Supp. of Rule 25(c) Motion [D.I. 182] at 3-4).

[redacted] Although Edwards' harm in this two-player market cannot be completely undone, the Court *can* stop CoreValve from perpetuating and escalating this damage from a U.S. plant.[2] An injunction will slow CoreValve's expansion, but it will not harm patients.

CoreValve obfuscates the issues by submitting declarations on alleged limitations of the Edwards device. These declarations miss the point by postulating a hypothetical market without the CoreValve device. [redacted][3]

Edwards would never support an injunction that jeopardized patients. Edwards' proposed large annulus "carve out" evidences this fact. Edwards is recognized as the global leader in the science of heart valves, its products are of the highest quality and it is committed to patient care.

II. ARGUMENT

A. The *eBay* Factors Weigh Heavily in Favor of a Permanent Injunction

1. Irreparable Harm to Edwards. Federal Circuit law is clear: "[a]lthough injunctions are tools for prospective relief designed to alleviate future harm, by its terms the first *eBay* factor looks, in part, at what has already occurred." *i4i Ltd. P'ship*, 598 F.3d at 862; *see also* EW Br. at 7-9. CoreValve does not seriously dispute that its "first-mover advantage"

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[2] Incredibly, CoreValve states that *all* it is doing is manufacturing in the U.S. (CV Br. at 2). Yet this is the very first act prohibited by §271(a).

[3] Should the Court consider CoreValve's declarations, Edwards' accompanying declarations correct their inaccuracies and demonstrate Edwards' ability to meet market demand. (*See generally* Wood Decl.; Thomas Decl.; Baumgartner Decl.; Horlick Decl.).

irreparably harmed Edwards in the past. (CV Br. at 8-9). Indeed, by awarding lost profits, the jury found that Edwards lost customers and had the capacity to fulfill their needs.[4]

CoreValve argues, however, that "[n]o presumption of irreparable harm attaches to a finding of infringement, even in a two-supplier market," and that "Edwards' failure to cite any prospective lost customers or other evidence of prospective irreparable harm alone defeats this motion." (CV Br. at 7).[5] CoreValve is wrong, for two reasons.

First, there can be no dispute that courts typically award permanent injunctions where, as here, the plaintiff practices its invention and the infringer is the only competition. (EW Br. at 8). CoreValve's cited cases involved multi-player markets and have no bearing here. *See eBay*, 547 U.S. at 390 (more than two parties competed in market); *Praxair*, 479 F. Supp. 2d at 442, 442 n.3 (while parties were only two mechanical-based systems in market, non-mechanical systems also competed).

Second, the "first-mover advantage" is not limited to CoreValve's past infringing activity. CoreValve's continued expansion irreparably harms, and will continue to irreparably harm, Edwards both financially and reputationally. (EW Br. at 7, 12; Leonard Trial Tr. at 962:4-

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4 [redacted] CoreValve argues that Edwards has been "limited by training capacity." (CV Br. at 7). The jury already rejected this argument when it awarded Edwards its lost profits. And [redacted] trial testimony made clear that Edwards' current training capacity can satisfy market demand. (*See* Wood Trial Tr. [D.I. 328] at 519:12-18, 587:2-7; [redacted] Leonard Trial Tr. [D.I. 329] at 965:4-967:8; [redacted] Moreover, there is no dispute that Edwards has sufficient manufacturing capacity. (*See* Wood Trial Tr. at 515:12-519:4; [redacted].

5 It should be observed that there is no categorical rule that Edwards must demonstrate prospective irreparable harm. See *Metro-Goldwyn-Mayer Studios, Inc.* v. *Grokster, Ltd.*, 518 F. Supp. 2d 1197, 1214 n.18 (C.D. Cal. 2007) ("Had the Supreme Court wanted district courts to analyze the irreparable harm that might flow from future infringements, it could have . . . easily said so.").

23; Leonard Decl. ¶¶ 4-6, 8; Wood Decl. ¶¶ 5, 6). CoreValve's own declarations prove the continued harm of the first-mover advantage. (*See, e.g.,* Blackman Decl. ¶ 5 (A429); Reimers Decl. ¶ 4 (A665)). Accordingly, CoreValve's reliance on *Advanced Cardiovascular*, *IMX* and *Voda* is misplaced. (CV Br. at 7-8). In each case, the patentee failed to proffer any evidence of its own irreparable harm. Here, CoreValve's unlawful first-mover advantage will be as damaging going forward as it has been in the past.[6]

2. Monetary Relief Is Inadequate. CoreValve does not refute that where, as here, the infringer is the patentee's only competition, courts have repeatedly held monetary damages insufficient. (EW Br. at 10). Relying on *Praxair*, CoreValve claims "[n]o injunction should issue where the plaintiff cannot 'iterate specific reasons why the infringement cannot be compensated for with a money award.'" (CV Br. at 9). But *Praxair*'s support for this proposition is *TiVo Inc.* v. *EchoStar Commc'ns Corp.*, 446 F. Supp. 2d 664 (E.D. Tex. 2006), where the court ordered a permanent injunction because "customers tend to remain loyal to the company from which they obtained their first DVR recorder, 'shaping the market to [p]laintiff's disadvantage and result[ing] in long-term customer loss.'" *Praxair*, 479 F. Supp. 2d at 444. This first-mover advantage described in *TiVo* is the very same harm suffered by Edwards, and is not compensable with money damages. (EW Br. at 7, 12; Leonard Decl. ¶¶ 4-6).

[redacted]

[redacted]

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6 CoreValve argues that failure to seek a preliminary injunction should be considered on irreparable harm. (CV Br. at 9). The Federal Circuit does not support such an approach. *See MercExchange, L.L.C.* v. *eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005) ("[W]e do not agree . . . that [the patent owner's] failure to move for a preliminary injunction militates against its right to a permanent injunction."), *vacated and remanded on other grounds*, 547 U.S. 388 (2006).

[redacted][7]

Importantly, neither Edwards nor PVT has ever licensed transfemoral rights to the patent. (Wood Decl. ¶ 39, [redacted]

3. Balance of Hardships Favors Edwards. CoreValve ignores Edwards' loss of expansion and goodwill as a result of CoreValve's infringement. *See, e.g.*, *Ortho McNeil Pharm., Inc.* v. *Barr Labs., Inc.*, Civ. A. No. 03-4678, 2009 WL 2182665, at *10 (D.N.J. July 22, 2009) ("Not granting the injunction will cause Ortho substantial, irreversible lost profits, price erosion, loss of market share, lost jobs, and loss of goodwill."); Leonard Decl. ¶¶ 4-8.

CoreValve's hardship argument "borders on a contention that successful exploitation of infringing technology shields a party from injunctive relief, and the more successful it is, the more it should be shielded." *Broadcom Corp.* v. *Qualcomm Inc.*, No. 8:05-CV-00467, *slip op.* at 16 (C.D. Calif. Dec. 31, 2007) ([D.I. 996]) (Egan Decl. Ex. 4), *aff'd in relevant part*, 543 F.3d 683 (Fed. Cir. 2008). This argument is meritless. *See id.*; *i4i Ltd. P'ship*,

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[7] CoreValve also argues that the large annulus "carve out" proves that a license payment is "adequate compensation." (CV Br. at 10). This "carve out" addressed saving patient lives, (continued)

598 F.3d at 863 ("Microsoft is not entitled to continue infringing simply because it successfully exploited its infringement.").

CoreValve alleges it may incur two hardships [redacted],[8] and loss of goodwill. (CV Br. at 11). But "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain . . . ." *Windsurfing Int'l* v. *AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986).

Medtronic has repeatedly stated that CoreValve and its patients will suffer no harm if an injunction issues. (EW Br. at 12-13). [redacted] A willful infringer's *preference* not to be inconvenienced cannot outweigh a patentee's *right* to exclude its sole competitor from infringing. [redacted] Edwards should not have to suffer further while CoreValve dawdles.

CoreValve's self-inflicted "hardships" are far outweighed by the hardships Edwards will suffer if an injunction is denied. [redacted] Necessarily, this will increase Edwards' irreparable loss of sales, customers, resources and reputation caused

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not "adequate compensation." (EW Br. at 15-16).

[8] CoreValve improperly relies on two *preliminary* injunction decisions, *Datascope* and *American Cyanamid*, [redacted] In both cases, the courts denied *preliminary* injunctions for products where the defendant could suffer harm if preliminarily enjoined, but later prevailed on the merits. These are not the facts here. Validity and willful infringement have been established. CoreValve will not erroneously incur a reputation as a patent infringer – the jury already found that it is. Indeed, in *Datascope* the court did grant the preliminary injunction for one product because "validity and infringement . . . have been clearly established by a prior adjudication." *Datascope*, 611 F. Supp. at 894.

by CoreValve's first-mover advantage. (EW Br. at 11-12; Leonard Decl. ¶ 8).[9]

4. Public Interest: CoreValve's Product Will Still Be Available. CoreValve's opposition assumes CoreValve's product would be taken off the market. This is incorrect.[10]

[redacted] CoreValve's patients can be treated by Edwards, but for the patient population in Edwards' proposed "carve out." (EW Br. at 15-16; Wood Decl. ¶¶ 7-8, 11-19, 22, 27-31).

CoreValve's five doctor declarations are red herrings. They are also riddled with inaccuracies.[12] (CV Br. at 4; *see* Wood Decl.; Thomas Decl.; Baumgartner Decl.; Horlick

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9 The balance of hardships favors Edwards, [redacted]. *See* EW Br. at 13 (citing *Novozymes*, 474 F. Supp. at 613); *see also Eli Lilly & Co.* v. *Medtronic Inc.*, 7 U.S.P.Q.2d 1439, 1446 (E.D. Pa. 1988) ("The fact that Medtronic has ceased production of model 7210 does not prevent issuance of an injunction against any further infringement.").

10 Thus, of no application here are all of CoreValve's cases where the requested injunction would have removed the product from the market. *E.I. Du Pont de Nemours & Co.*, 835 F.2d at 278; *Kimberly-Clark Worldwide, Inc.*, 635 F. Supp. 2d at 882; *Bard Peripheral Vascular, Inc.*, 2009 WL 920300, at *9; *Advanced Cardiovascular*, 579 F. Supp. 2d at 561; *Cordis Corp.*, 2003 WL 22843072, at *2.

11 [redacted].

12 CoreValve's declarations allege that for some patients CoreValve is the "only option." (*See* Brecker Decl. ¶ 8 (A422); Danenberg Decl. ¶ 13 (A420); Meredith Decl. ¶ 7 (A426)). Only patients with annulus sizes larger than 25 mm, which, based on CoreValve's own data, account for only about 10% of CoreValve's patients, cannot currently be treated by Edwards' (continued)

Decl.). All ignore Edwards' introduction of the SAPIEN XT product in March 2010. (Wood Decl. ¶ 7). SAPIEN XT has the same delivery profile as the ReValving System, allowing Edwards to treat CoreValve's patient population (except for the 10% large annulus cases accounted for in the "carve out"). (*Id.* at ¶ 8). These declarations really address a few individual preferences for the CoreValve product. However, doctor preference is irrelevant. *Shiley, Inc.* v. *Bentley Labs., Inc.*, 601 F. Supp. 964, 970 (C.D. Cal. 1985) (declarations merely expressing preference for particular medical devices are insufficient to weigh against issuance of injunction). [redacted]

B. Response to CoreValve's Additional Arguments[13]

1. The Injunction Should Apply to the Extended Patent Term. CoreValve should be precluded from infringing until the patent expires, including any patent term extension. Federal Circuit law is clear that injunctions may extend through the patent term extension. *See Ortho-McNeil Pharm., Inc.* v. *Lupin Pharm., Inc.*, 603 F.3d 1377, 1381-82 (Fed. Cir. 2010) (affirming permanent injunction "during the extended term"). Moreover, this Court regularly issues injunctions that account for patent term extension. *See, e.g., Novozymes A/S* v. *Genencor Int'l, Inc.*, Civ. A. No. 05-160 (D. Del. Mar. 5, 2007) (Judgment Order [D.I. 231]) (injunction "until such time as the '031 Patent expires, including any extensions and regulatory exclusivities"); *see also In re: Alfuzosin Hydrochloride Patent Litig.*, No. 08-md-1941 (D. Del. Aug. 3, 2010) (Judgment [D.I. 176]) (injunction "until after the expiration date of the '491

SAPIEN and SAPIEN XT devices. (Edwards Br. at 15-16; Wood Decl. ¶¶ 7-14). Those patients are accounted for in the "carve out." [redacted]

[13] Edwards' request for an accounting and related relief was not opposed. (EW Br. at 16-17).

patent, plus any exclusivities afforded by 21 U.S.C. §355a(c)(1)(B)(iii)") (collectively attached to Egan Decl. as Exs. 5-6).

CoreValve nonetheless suggests that any extension may not support an injunction because "[t]he extension restores the patentee's rights only for the *product* that is the basis of the application, not the full scope of the claim." (CV Br. at 17) (emphasis original). This is not the law. An extension is not limited to Edwards' FDA approved product, but includes "any *use* approved for the product." 35 U.S.C. § 156(b)(1) (emphasis added); *see Pfizer Inc.* v. *Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1366 (Fed. Cir. 2004). Both Edwards' SAPIEN valve and CoreValve's ReValving System are transcatheter heart valves. CoreValve's ReValving System will therefore fall within the extended patent term of the '552 Patent.[14]

2. The Injunction Should Not Be Stayed Pending Appeal. To warrant a stay, "a movant must establish a strong likelihood of success on the merits or, failing that[,] must demonstrate that it has a substantial case on the merits and that the harms factors militate in its favor." *iLight Techs., Inc.* v. *Fallon Luminous Prods. Corp.*, No. 2009-1342, 2009 WL 1939187, at *1 (Fed. Cir. July 1, 2009) (affirming district court's denial of stay pending appeal).

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14 [redacted]

CoreValve argues that market conditions may change during the extension, and that Edwards should petition the Court to extend the injunction at that time. (CV Br. at 17; [redacted]. CoreValve has it backwards. If exceptional circumstances arise that require relief from the injunction, CoreValve may petition the Court under Fed. R. Civ. P. 60(b) to modify the injunction. *See Coltec Indus., Inc.* v. *Hobgood*, 280 F.3d 262, 273 (3d Cir. 2002).

CoreValve has made no such showing. (*See, e.g.,* Edwards' Briefs in Opp'n to CoreValve's Motions for JMOL and New Trial [D.I. 369, 370]).[15]

3. The Injunction Should Prohibit All Modes of Infringement. CoreValve argues that any injunction issued should exclude § 271(f) infringement because it was only held to willfully infringe § 271(a). (CV Br. at 17-18). But an injunction may encompass other modes of infringement. *See, e.g., Pac-Tec, Inc.* v. *Amerace Corp.*, 903 F.2d 796, 802 (Fed. Cir. 1990) (declining to limit injunction to only direct infringement under § 271(a) because "the district court has power to grant an injunction in accordance with the principles of equity to prevent the violation of any rights secured by patent."). Edwards therefore requests the Court enjoin CoreValve from infringing any of the rights secured by the '552 Patent, including those rights protected under § 271(f).[16]

III. CONCLUSION

For the reasons set forth herein and in its opening brief, Edwards respectfully requests that the Court issue a permanent injunction and order an accounting and related relief, as set forth in Edwards' Proposed Order [D.I. 356].

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[15] If not extended, the '552 Patent will expire in May 2012. The short time left is further reason to deny a stay. *See* EW Br. at 9-10; *S.C. Johnson, Inc.* v. *Carter-Wallace, Inc.*, No. 81 Civ. 1081, 1985 WL 501, at *5 (S.D.N.Y. Mar. 29, 1985), *rev'd on other grounds*, 781 F.2d 198 (Fed. Cir. 1986) (with only 32 months left on patent, "a further loss of exclusivity for even a portion of that time would constitute great harm to [patentee]"); *Corning Glass Works* v. *Sumitomo Elec. U.S.A., Inc.*, 674 F. Supp. 1074, 1077 (S.D.N.Y. 1987) (denying stay of injunction pending appeal; patent had less than a year and a half to run).

[16] [redacted] Edwards agreed to a mutual post-trial exchange of discovery, but CoreValve refused to produce its documents. Edwards produced documents concerning its newly introduced SAPIEN XT product unilaterally. (*See* Egan Decl. at Ex. 7).

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